K092012

510 (k) Summary

Submitted by:	priMED #900, 10707-100 Ave. Edmonton, Alberta 780-497-7600
Contact Person:	Dr. Raymond G. Marusyk
Date Prepared:	June 10, 2009
Proprietary Name:	PRIMAGARD DELTA Surgical Mask
Common Name:	Surgical Mask
Classification Name:	Surgical Mask, 878.4040; Product code FXX
Predicate Device:	Surgical Mask 510(k) #K081633

SEP 2 5 2009

Description of the Device: These surgical masks are deltoid shape, waterfall-pleated devices manufactured from selected non-woven materials (polypropylene and wet-laid cellulose) designed to provide optimal breathability, particulate filtration and a fluid-penetration barrier relative to the degree of protection required during intended use.

Intended Use of the Device: PRIMAGARD™ Delta Surgical Masks are surgical apparel as identified in 21 CFR 878.4040 and are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Technological Characteristics: The PRIMAGARD™ Delta Surgical Masks are technologically similar to the predicate device (K081633) in that both devices consist of non-woven barrier materials selected and arranged in such a manner as to provide, at the time of design, and under the conditions of use, optimal breathability and particulate filtration. The PRIMAGARD™ Delta Masks incorporate a deltoid design and include an elastomeric non-woven material as piping and headband.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Raymond G. Marusyk
Director, Design and Development
PriMED Medical Products, Incorporated
#900, 10707-100 Avenue
Edmonton, Alberta
CANADA T5J-3M1

SEP 25 2009

Re: K092012
Trade/Device Name: PRIMAGARD Delta Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: September 15, 2009
Received: September 17, 2009

Dear Mr. Marusyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/Reporta Problem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K092012

Device Name PRIMAGARD Delta Surgical Masks

Indications for Use PRIMAGARD Delta Surgical Masks are surgical apparel as identified in 21 CFR 878.4040 and are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801. 109)

Rahil Parekh

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092012